CAUSE NO. _____

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
JENNIFER JACKSON d/b/a/	§	DALLAS COUNTY, T E X A S
BODY CLEANSE DAY SPA	§	
Defendant.	§	____ JUDICIAL DISTRICT

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, plaintiff, acting by and through Attorney General GREG ABBOTT, filing Plaintiff's Original Petition complaining of and against Defendant JENNIFER JACKSON d/b/a BODY CLEANSE DAY SPA ("herein after Defendant JENNIFER JACKSON" or "Defendant"), based on her false advertising and misrepresentations regarding the use of prescription colon irrigation systems, including rectal nozzles, and would respectfully show the court the following:

JURISDICTION

1. This suit is brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the STATE OF TEXAS and in the public interest under the authority granted to him by §431.047 (b) of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. ("TFDCA") and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of Health of the State of Texas and his authorized agents find that Defendant has violated and is threatening to violate provisions of §431.021 of the TFDCA.

2. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the State of Texas under the authority granted to him by §17.47 of the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*, ("DTPA") upon the grounds that Defendant has engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by §17.46 (a) and (b) of the DTPA.

PARTY DEFENDANT

3. Defendant JENNIFER JACKSON is an individual doing business in this state as BODY CLEANSE DAY SPA at 4103 Swiss Avenue, Dallas, Texas 75204, and may be served with process by serving her at her business address.

VENUE

4. Venue of this action lies in Dallas County on the basis of §17.47(b) of the DTPA by virtue of the fact that Defendant engaged in the business of operating a health-related clinic using prescription medical devices in Dallas County, Texas.

5. Venue of this action lies in Dallas County on the basis of §431.047 (c) and §431.0585(d) of the TFDCA by virtue of the fact that Defendants are engaged in the business of operating a health-related clinic using prescription medical devices in Dallas County, Texas.

PUBLIC INTEREST

6. By reason of the institution and operation of the unlawful practices set forth herein, Defendant has and will cause immediate and irreparable injury, loss and damage to the State of Texas, and its citizens, and will also cause adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

TRADE AND COMMERCE

7. Defendant is engaged in trade and commerce, as that term is defined by §17.45(6) of the DTPA, in that she is or was engaged in the business of advertising and/or marketing and delivering colon cleansing services in Texas.

NOTICE BEFORE SUIT

8. Pursuant to §17.47(a) of the Deceptive Trade Practices Act, contact has been made with the Defendant herein to inform her of the unlawful conduct alleged herein, by letter mailed by certified mail, return receipt requested.

ACTS OF AGENTS

9. Whenever in this petition it is alleged that Defendant did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by the officers, agents or employees of said Defendant, and in each instance, the officers, agents or employees of said Defendant that were then authorized to and did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of the Defendant.

OVERVIEW OF DEFENDANT'S OPERATION

10. Defendant advertises and/or markets and provides colon cleansing services, using prescription colon irrigation systems, including rectal nozzles[1], and ozone spa treatment using unapproved Ozone Spa devices in Dallas, Texas. Defendant advertised or marketed customers to have colon cleansing for constipation, other bowel problems, weight loss, and/or general well-being in the Dallas, Texas area, as shown below.

11. Defendant advertises and promotes the use of colon irrigation systems that FDA

[1]In this petition, the phrase "prescription colon irrigation system" includes all parts of the system required to provide colon cleansing, including rectal nozzles, as the nozzles are accessories of the system and cannot be used separately from the system.

has only cleared for a Class II intended use, as defined in 21 CFR 876.5210, for colon cleansing when medically indicated, such as before radiological or endoscopic examinations. Based upon this intended use, FDA has limited the use of all colon irrigation systems cleared for marketing to prescription use only. Therefore, all colon irrigation systems cleared for marketing by FDA are required to bear the statement on their labels that "Federal Law restricts this device to sale by or on the order of a _____", the blank to be filled in with the word 'physician, dentist, veterinarian, or with the description designation of any other practitioner licensed by the law of the State in which he practices to use and order the use of the device[2].

12. In a Warning Letter to Colon Therapeutics, Inc., the manufacturer of Defendant's prescription colon irrigation systems, FDA informed Defendants that "(w)hen FDA cleared the 510(k)s for the Jimmy John rectal nozzles, an accessory of the Jimmy John colonic irrigation system, we indicated that our clearance was limited to prescription use only." FDA continues that both the colon irrigation system and the rectal nozzles were cleared for the same intended use as defined in 21 CFR 876.5220 and concludes that the Jimmy John III colon irrigation system is misbranded because its labeling fails to bear the prescription legend.

13. Defendant JENNIFER JACKSON is not a licensed practitioner as defined by 25 T.A.C. §229.433 (22) or §483.001(12) of Texas Dangerous Drug Act.

14. Defendant purchased and received in commerce two prescription colon irrigation systems and thousands of prescription rectal nozzles without authorization from a licensed practitioner to purchase or possess them as required by state and federal law, and, therefore, misbranded them.

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[2]Under Texas law, the only practitioner licensed to use prescription colon irrigation systems on humans are those licensed by the Texas Board of Medical Examiners. Therefore, in this petition, when the term "practitioner" is used, it refers only to those persons licensed by the Texas Board of Medical Examiners.

15. Defendant used these prescription colon irrigation systems to provide colon cleansing to hundreds of patients in Dallas, Texas without a licensed practitioner ordering a procedure on a patient and without a licensed practitioner supervising her use of the prescription medical devices. This use without practitioner involvement, as required by state and federal law, misbranded Defendant's devices.

16. Defendant used these prescription colon irrigation systems for other purposes than the approved intended use of colon cleansing when medically indicated as shown below. Defendant's use of these prescription colon irrigation systems for colon cleansing for general well being, a use that has not been approved by the FDA as safe and effective, adulterated these devices.

17. Defendant also provided ozone spa treatments that injected ozone into a steam bath cabinet using Ozone Spa devices without any evidence that the Federal Food and Drug Administration had approved the marketing of these medical devices for use with ozone for self-treatment for any purpose.

18. Defendant advertises and markets colon cleansing to generate patients for these services. Defendant misbrands her prescription colon irrigation systems under state and federal law by advertising and promoting them for uses other than the FDA approved use.

19. Defendant advertises and/or markets and promotes ozone spa treatments to generate patients for these services using unapproved ozone spa treatment devices.

Inspection of December 19, 2002:

20. On December 19, 2002, an investigator from the Texas Department of Health ("TDH") inspected Defendant's facility as a result of obtaining Defendant's name as a colon cleansing clinic that may be participating in a study, not approved by FDA, to reclassify colon irrigation systems for general well being.

21. TDH determined that Defendant purchased and received in commerce in Dallas, Texas two Jimmy John III prescription colon irrigation systems from Colon Therapeutics, Inc., and Jimmy Girouard, who also solicited Defendant to participate in a study unapproved by FDA to reclassify these devices for general well-being, and that all of these devices are considered by FDA to be prescription devices.

22. TDH determined that Defendant did not have a licensed practitioner to authorize her to purchase or possess the two prescription colon irrigation systems.

23. TDH also determined that Defendant did not have a licensed practitioner ordering the colon cleansing procedures for patients or supervising Defendant's use of the prescription colon irrigation systems to perform colon cleansing for any purpose.

24. TDH also determined that Defendant performed colon cleansing for a variety of reasons, such as constipation, other bowel problems, and weight loss, as well as for general well-being. In addition, TDH determined that Defendant did not develop, maintain, or implement written procedures to comply with medical device reporting (MDR) requirements.

25. TDH determined that Defendant performed colon cleansing for approximately 100 patients per month but could not review any files due to Defendant keeping the patient files at her residence. TDH also determined that Defendant performed ozone spa treatments for approximately 20 patients a month.

26. TDH issued a "Notice of Detention" on December 19, 2002, notifying Defendant that the Texas Department of Health had detained Defendant's two prescription colon irrigation systems and two Ozone Spa devices after determining that these devices were adulterated, misbranded, and/or violated additional provisions of the TFDCA.

27. In addition, Defendant was notified by the Notice of Detention form which cited to Section 431.021(j) of the Texas Health and Safety Code that the use, removal, or disposal of a

detained article from the premises by sale or otherwise without written permission from the Commissioner of Health, an authorized agent, or the court to be an unlawful and prohibited act.

Inspection of January 3, 2003:

28. On January 3, 2003, a follow-up inspection was conducted by the TDH at Defendant's office. The investigator inspected Defendant's Jimmy John III rectal nozzles purchased from Colon Therapeutics, Inc., and found that the labels affixed to them indicated that federal law restricts the nozzles to sale by or on the order of a physician or health care practitioner.

29. TDH reviewed a sample of patient records provided by Defendant and determined that colon cleansing was performed since Defendant began her colon cleansing business using prescription colon irrigation systems on all patients without orders from a licensed practitioner.

30. TDH also determined that Defendant was not a practitioner licensed to use or order the use of prescription colon irrigation systems and that Defendant was not supervised by a practitioner licensed to use or order the use of prescription colon irrigation systems. Defendant's "Informed Consent Form" states that neither the owner, JENNIFER JACKSON, nor any of the associates are medical doctors.

31. TDH also determined that Defendant used prescription colon irrigation systems to treat its clients for constipation or bowel cleansing to aid weight loss even though Defendant's "Informed Consent Form" for colon cleansing requires the patient to acknowledge that "...the medical devices are intended for colon cleansing when medically indicated such as before radiological or endoscopic examinations". In addition, some of Defendant's "Informed Consent Form" require that the patient acknowledge that "...the medical advice used in this procedure is intended for use in Colon Irrigation, and that these devices are intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations".

32. Defendant also used a "Release Waiver of Full Liability" for treatment using the Ozone Spa for a "...safe ozonated steam session" and for the use of the Ozone Spa for "...my own self-treatment sessions." This release form also requires the patient acknowledge "...that ozone can amplify the effects of drugs and supplements due to increased cellular absorption."

33. TDH issued a "Notice of Detention" on January 3, 2003, notifying Defendant that the Texas Department of Health detained 69 Jimmy John III rectal nozzles after determining that these devices were adulterated, misbranded, and/or violated additional provisions of the TFDCA.

OVERVIEW OF REGULATION OF PRESCRIPTION MEDICAL DEVICES

34. The Texas Food, Drug, and Cosmetic Act ("TFDCA") lists acts and the causing of acts that are unlawful and prohibited, including, but not limited to, misbranding medical devices in commerce, adulterating medical devices in commerce, and the dissemination of any false advertisement. TDH determines if the use of a medical device violates any prohibited acts depending on the classification and regulation of each medical device by the Federal Food and Drug Administration ("FDA").

FDA Regulates and Classifies Medical Devices According to Intended Use

35. FDA regulates and classifies medical devices for use in humans according to their intended use, relying upon the manufacturer or distributor's labeling of the device to determine its intended use. FDA is responsible for classifying and approving medical devices after they determine whether they are safe and effective for their stated intended uses.

36. FDA has classified colon irrigation systems intended for "colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations" as Class II medical devices when used for this purpose in 21 C.F.R. §876.5220 (b)(1). Colon irrigation devices are described as usually consisting of a container for fluid; the tubing; the nozzle; a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled; a

console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes; and electrical power to heat the water.

37. FDA approved the colon irrigation system used by Defendant, the Jimmy John III colon irrigation system and the Jimmy John Rectal Nozzle, as "substantially equivalent" to other pre-existing colon irrigation devices used for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations based on premarket notification submissions to the FDA pursuant to § 510(k) of the FFDCA, 21 U.S.C. § 360(k). Therefore, these devices are Class II medical devices by regulation for this purpose and can only be used for the approved intended use for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

38. FDA has also classified colon irrigation systems for other uses than the intended use authorized in 21 C.F.R. §876.5220 (b)(1). FDA classified these prescription colon irrigation systems as class III medical devices when the intended use is for "other uses, including colon cleansing routinely for general well being" as shown in 21 C.F.R. §876.5220 (b)(2).

39. FDA's classification of prescription colon irrigation systems as Class III medical devices requires that any colonic irrigation system to be used for purposes other than those approved in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being shall have an approved premarket approval ("PMA") in effect before being placed in commercial distribution to show that the device is safe and effective for the new intended use . (21 C.F.R. §876.5220 (c)).

40. FDA requires that, unless specifically exempted, a medical device must have "adequate directions for use" as defined in 21 C.F.R. § 801.5 to mean directions under which the layperson can use a device safely and for the purposes for which it is intended. Unless subject to

an exemption, a medical device must have "adequate directions for use" or it cannot be sold to or used by a lay person.

FDA Considers All Colon Irrigation Devices To Be Prescription Medical Devices

41. FDA defines a prescription device in 21 C.F.R. § 801.109 to be a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared.

42. The FDA regulations create an exemption from the requirement of having "adequate directions for use" for prescription medical devices in 21 C.F.R. § 801.109. To qualify for an exemption from "adequate directions for use", a medical device must be in the possession of a practitioner licensed by state law to use or order the use of such device; sold only to or on the prescription or other order of such practitioner for use in professional practice; and the label has to bear the statement "Caution: Federal law restricts this device to sale by or on the order of a _____, to be filled in with the descriptive designation of any practitioner licensed by state law in which he practices to use or order the use of the device.

43. The FDA considers that the prescription colon irrigation systems possessed and used by Defendant are prescription medical devices, as defined in 21 C.F.R. 801.109, and these devices must comply with all the requirements as cited in paragraph 42 above in order to be exempted from "adequate directions for use". Because the colon irrigation devices used by Defendant are prescription devices, adequate directions for safe use by a layperson cannot be written for these devices, and therefore must comply with the exemption requirements in paragraph 42 or they are not cleared for marketing by FDA.

44. In addition, prescription medical devices are restricted devices because they are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Restricted devices pursuant to 25 T.A.C. §229.433 (27) are devices that are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Because Defendant's prescription colon irrigation systems are prescription medical devices, under Texas law her devices are also restricted devices since they are subject to certain controls related to the sale, distribution, or use, as defined in 25 T.A.C. §229.433 (23) and (27).

45. Prescription colon irrigation systems are "dangerous drugs" pursuant to §483.001 (2) of the Texas Dangerous Drug Act because these devices bear or are required to bear a legend to comply with federal law regarding their sale as prescription medical devices pursuant to 21 C.F.R. § 801.109.

46. Under Texas law, only those practitioners listed in § 483.001(12) of the Texas Dangerous Drugs Act, also defined in 25 T.A.C. §229.433 (22), are authorized to purchase, possess, use or order the use of prescription or restricted medical devices, including prescription colon irrigation systems. The only practitioners licensed in Texas who can purchase, possess, use or order the use of prescription colon irrigation systems on humans in the course of their professional practice are those practitioners licensed by the Texas Board of Medical Examiners.

47. Defendant is not a practitioner as defined by 25 T.A.C. §229.433 (22) or §483.001(12) of Texas Dangerous Drug Act and therefore prescription colon irrigation systems in her possession and use are not exempted from having adequate directions for use.

DEFENDANT'S DEVICES ARE MISBRANDED

48. As set out in paragraphs 1 through 47 and incorporated herein, Section 431.112(f)(1) of the TFDCA provides that a device is misbranded unless its labeling bears

adequate directions for use or unless the device has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services. Since the prescription colon irrigation systems used by Defendant cannot bear instructions for safe use by a layperson and only are exempt from this requirement pursuant to 21 C.F.R. § 801.109, Defendant is required to have a licensed practitioner to purchase and possess, to order the procedure, and to supervise the use of prescription colon irrigation systems.

49. Defendant is not a licensed practitioner as defined by §483.001(12) of The Dangerous Drug Act nor did she have a licensed practitioner authorizing her purchase and possession, ordering colon cleansing procedures for patients, or supervising the colon cleansing procedures.

50. Defendant's purchase and possession of prescription colon irrigation systems; lack of written orders for colon cleansing procedures for each patient; and the use of prescription colon irrigation systems without authorization and supervision of a practitioner/physician licensed in Texas misbrands these device pursuant to § 431.112 (f) of the TFDCA.

51. Subsequently, Defendant performed colon cleansing without authorization from a practitioner licensed in Texas to purchase, possess, or use prescription colon irrigation systems which are also restricted devices, as defined in by 25 T.A.C. §229.433 (27), since they are subject to certain controls related to the sale, distribution, or use. Therefore, Defendant's purchase, possession, and use of prescription colon irrigation systems as restricted devices without authorization, a written order for colon cleansing procedures, and supervision by a practitioner licensed in Texas also misbrands these device pursuant to § 431.112 (r) of the TFDCA.

52. Under the terms of § 431.021(b) of the TFDCA, the misbranding of any device in commerce in Texas is unlawful and prohibited. Defendant's purchase, possession, and use of prescription and restricted colon irrigation systems without authorization and supervision by a

practitioner licensed in Texas misbrand these devices in Texas.

53. Each colon cleansing using prescription colon irrigation systems that Defendant has performed in Texas without an order from a licensed practitioner or without supervision by practitioner licensed in Texas violates Texas law and is prohibited and unlawful because this use without such an order or supervision from a licensed practitioner misbrands the prescription colon irrigation systems.

DEFENDANT'S DEVICES ARE ADULTERATED

54. As set out in paragraphs 1 through 53 and incorporated herein, prescription colon irrigation systems used for other uses (than those stated in 21 C.F.R. §876.5220 (b)(1)), including general well being purposes, have not been approved previously by FDA and are, therefore, not preamendment devices and are by regulation (21 C.F.R. §876.5220 (b)(2)) and by statute classified as Class III medical devices and may not be marketed without an approved application for Premarket Approval ("PMA") under section 515 of the Federal Food, Drug, and Cosmetic Act. FDA has not approved any application for PMA for colon irrigation devices for any purposes, including general well being.

55. The prescription colon irrigation devices used by Defendant are Class III medical devices when used for purposes other than those stated in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being, and require premarket approval, or must fall into an exemption from such approval, before they can be used in the marketplace. FDA must review each Class III medical device to determine if it is safe and effective for its use(s) before the device can be introduced into commerce.

56. Defendant's prescription colon irrigation systems are Class III medical devices when used for other uses (than those stated in 21 C.F.R. §876.5220 (b)(1)), including general well being, and were required to receive premarket approval from FDA, but are used in commerce

even though they did not receive such approval. (21 U.S.C.A. §351(f) (1)(A), section 501(f)(1)(A) of the FFDCA). A device is adulterated if it is a Class III medical device, whether by statute or regulation, and is in the marketplace without receiving approval from FDA.

57. Defendant's prescription colon irrigation systems are adulterated under state law, according to §431.111(f)(1)(A) of the TFDCA. Section 431.111 states that a device shall be deemed to be adulterated :

> **(**f)(1) if it is a class III device:
>
> (A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and
>
> (ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or
> (II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn.

58. Under the terms of § 431.021(b) of the TFDCA, the adulteration of any device in commerce in Texas is unlawful and prohibited. Defendant violates § 431.021(b) of the TFDCA and adulterates her prescription colon irrigation devices with each use that FDA codifies as a Class III medical device use, including general well being, since these devices have not been approved through pre-market approval as required by FDA to show their safety and effectiveness for Class III uses.

DEFENDANT'S ADVERTISEMENTS ARE FALSE, MISLEADING OR DECEPTIVE

59**.** As set out in paragraphs 1 through 58 and incorporated herein by reference, Defendant JENNIFER JACKSON represented that her prescription colon irrigation devices have uses other than those for which FDA has allowed the devices to be sold or used, including an aid for weight loss and for general well being. Defendant's representations for the use of prescription

colon irrigation systems for unapproved uses constitutes false advertisements in violation of § 431.021(f) of the TFDCA.

60. Defendant also has violated § 431.021(f) of the TFDCA because Defendant's representations of the illegal use of her medical devices constituted false advertisements under the TFDCA because she solicited persons to purchase services which violated § 431.021(b) of the TFDCA.

61. Defendant promoted the unapproved use of prescription colon irrigation systems as an aid to weight loss and for general well-being although these devices are not intended for self-medication or for use without practitioner supervision and ordering and without disclosing that these acts are unlawful and prohibited by the TFDCA.

62. Such representations listed above constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendant's services through her unapproved uses of prescription colon irrigation systems without involvement of a practitioner licensed in Texas.

63. Any such advertisement by Defendant of a prescription medical device without disclosing that a licensed practitioner must order the colon cleansing procedure to be administered with prescription colon irrigation systems and for unapproved uses are declared to be false by the terms of §431.182(a) of the TFDCA.

PROHIBITED ACTS

64. Defendant, as set out in paragraphs 1 through 63 and incorporated herein by reference, have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.021 of the TFDCA:

a. Introducing and delivery into commerce a misbranded or adulterated prescription colon irrigation system with each use of Defendant's prescription colon irrigation systems, in violation of §431.021(a);

b. Misbranding of a prescription colon irrigation system in commerce, in violation of §431.021(b);

c. Adulteration of a prescription colon irrigation system in commerce, in violation of §431.021(b)

d. Receiving in commerce a prescription colon irrigation system that is adulterated or misbranded, in violation of §431.021(c);

e. Introducing and delivery into commerce an adulterated Ozone Spa device with each use of Defendant's unapproved Ozone Spa device, in violation of §431.021(a);

f. Failing to develop, maintain, and implement written procedures to comply with medical device reporting (MDR) requirements in 21 CFR § 803 and Section 519 of the federal Act, in violation of §431.021(t)(1)(B)

g. Disseminating false advertising, in violation of §431.021(f).

VIOLATIONS OF THE DTPA

65. Defendant, as set out in paragraphs 1 through 64 and incorporated herein by reference, in the course and conduct of trade and commerce, have directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

a. Causing confusion as to the approval of a good by using prescription colon irrigation systems without the authorization or supervision of a practitioner licensed in Texas;

b. Failing to disclose that prescription colon irrigation systems are only to be sold under the order of a practitioner licensed in Texas and Defendant's possession of the devices violate state law;

c. Failing to disclose that prescription colon irrigation systems are only to be used under the supervision of a practitioner licensed in Texas and Defendant does not have the required supervision;

d. Failing to disclose that colon cleansing using prescription colon irrigation systems can only be performed upon the order of a licensed practitioner in Texas;

e. Falsely representing to a consumer that colon cleansing using prescription colon irrigation systems can legally be performed without the supervision or order of a practitioner licensed in Texas;

f. Failing to disclose that federal and state law prohibit colon cleansing using prescription colon irrigation systems for general well-being or for weight loss because this use has not been proven to be safe and effective to FDA;

g. Falsely representing that colon cleansing using prescription colon irrigation system is available to the general public when it is not;

h. Falsely representing that ozone steam spa treatments using Ozone Spa devices is safe when FDA has not approved any devices for such use; and

i. Failing to disclose that federal and state law prohibit ozone steam spa treatments using Ozone Spa devices because these devices have not been proven to be safe and effective to FDA for any intended use.

66. Moreover, the Consumer Protection Division has reason to believe that the above actions specifically violate §17.46 (a) and the following provisions of §17.46 of the DTPA:

(b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;

(b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;

(b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

(b)(24) failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

INJURY TO CONSUMERS

67. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendant has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

CONTINUING VIOLATIONS

68. By reason of the institution and continued operation of the acts and practices described in paragraphs 1 through 67 above, Defendant has violated and will continue to violate

the laws as hereinabove alleged. Defendant JENNIFER JACKSON, unless restrained by this Honorable Court, will continue violating the laws of the State of Texas and injury, loss and damage will result to the State of Texas and to the general public. Defendant has violated and continue to violate these sections of the TFDCA and the DTPA.

PRAYER

69. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendant JENNIFER JACKSON be cited according to law to appear and answer herein; that after due notice and hearing a TEMPORARY INJUNCTION be issued and upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendant individually and by their agents, servants, employees, and representatives from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

a. Introducing and delivering into commerce misbranded or adulterated prescription colon irrigation systems, including rectal nozzles;

b. Misbranding or adulteration of prescription colon irrigation systems, including rectal nozzles in commerce;

c. Receiving in commerce prescription colon irrigation systems, including rectal nozzles that are adulterated or misbranded;

d. Disseminating false advertising about prescription colon irrigation systems, including rectal nozzles;

e. Purchasing and possessing prescription colon irrigation systems, including rectal nozzles, without a practitioner licensed under Texas law to purchase and possess such devices;

f. Using prescription colon irrigation systems, including rectal nozzles, without the supervision of a practitioner licensed by Texas law to use such devices;

g. Using prescription colon irrigation systems, including rectal nozzles, without a written order for each use from a practitioner licensed under Texas law to order the use of such prescription devices;

h. Using prescription colon irrigation systems, including rectal nozzles for treating diseases of the body or for uses, including general well being for which FDA has not approved these devices;

i. Failing to comply with federal medical device reporting requirements, as required by 21 CFR § 803 and Section 519 of the federal Act;

j. Falsely advertising or falsely representing that prescription colon irrigation systems, including rectal nozzles, can be self-administered;

k. Falsely advertising or falsely representing that prescription colon irrigation systems, including rectal nozzles, are effective for treating diseases of the body for which FDA has not approved these devices;

l. Falsely advertising or falsely representing that prescription colon irrigation systems, including rectal nozzles, are effective for uses, including general well being, for which FDA has not approved these devices;

m. Failing to provide a notice required by Section 510 (k) of the Federal Act or file an application for premarket approval as required by Section 515 of the Federal Act prior to introducing into commerce a prescription colon irrigation system, including a rectal nozzle, for a new or unapproved use;

n. Failing to comply with any requirement prescribed under Section 520(g) of the Federal Act and furnishing any notification or information required by or under Section 519 or 520(g) of the Federal Act;

o. Causing confusion as to the approval of a good by allowing consumers to use prescription colon irrigation systems, including rectal nozzles, for self-use;

p. Failing to disclose that the prescription colon irrigation systems used for colon irrigation are only to be used under the written order and supervision of a practitioner licensed in Texas;

q. Introducing and delivering into commerce adulterated Ozone Spa device with each use of Defendant's unapproved Ozone Spa device;

r. Falsely representing that ozone steam spa treatments using Ozone Spa devices is safe when FDA has not approved any devices for such use;

s. Failing to disclose that federal and state law prohibit ozone steam spa treatments using Ozone Spa devices because these devices have not been proven to be safe and effective to FDA for any intended use; and

t. Failing to provide written notice to any agent, servant, employee or representative of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein.

70. Plaintiff further prays that upon final hearing that this Court order Defendant JENNIFER JACKSON, within 30 days of the order signed by the Court, at her own expense to destroy all devices pursuant to § 431.050 of the TFDCA, currently detained by TDH, unless said devices are brought into compliance with Chapter 431 and have been released from detention by TDH based upon Defendant's assurance that the devices will be used in a manner consistent with the law and the terms of this injunction or transferred or sold to a licensed practitioner for the practitioner's use in his/her own practice if the device or product has been approved by the FDA.

71. Plaintiff further prays that upon final hearing this Court order Defendant JENNIFER JACKSON to pay civil penalties to the State of Texas up to $25,000 per violation per day for each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

72. Plaintiff further prays that upon final hearing that this court order Defendant JENNIFER JACKSON to pay to the State of Texas and to the TEXAS COMMISSIONER OF HEALTH their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees pursuant to § 431.047(d) of the TFDCA.

73. Plaintiff further prays that upon final hearing this Court order Defendant JENNIFER JACKSON to restore all money or other property taken from identifiable persons by means of Defendant JENNIFER JACKSON's unlawful acts or practices, or, in the alternative, award judgment for damages to compensate identifiable persons for such losses as provided in §17.47(d) of the DTPA.

74. Plaintiff further prays, that upon final hearing, this Court order Defendant JENNIFER JACKSON to pay civil penalties of not more than $20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

75. Plaintiff further prays that upon final hearing this Court order Defendant JENNIFER JACKSON to pay an additional amount in civil penalties, not to exceed a total of $250,000.00, to the State of Texas, for any act or practice that was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred as provided in §17.47(c)(2) of the DTPA.

76. Plaintiff further prays that upon final hearing that this Court order Defendant JENNIFER JACKSON to pay to the STATE OF TEXAS attorney fees and to pay the costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

77. Plaintiff further prays that the court set this matter for trial and upon final hearing issue a permanent injunction against Defendant JENNIFER JACKSON.

78. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may be justly entitled.

Plaintiff State of Texas

GREG ABBOTT
Attorney General of Texas

BARRY MCBEE
First Assistant Attorney General

ED D. BURBACH
Deputy Attorney General for Litigation

PAUL D. CARMONA
Assistant Attorney General
Chief, Consumer Protection Division

_____

JOYCE WEIN ILIYA
Assistant Attorney General
Consumer Protection Division
State Bar No. 00784319
1600 Pacific Avenue, Suite 1700
Dallas, Texas 75201-3513
(214) 969-7639, ext. 111
Facsimile: (214) 969-7615
Attorneys for the State